

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume VIII Issue 8

September 2003

10th Annual Clinical Laboratory Conference

by Leonard Kargacin

The 10th Annual Clinical Laboratory Conference will be held on November 10, 2003 at the Seattle Marriott Hotel near Sea-Tac International Airport. This is an excellent opportunity to hear about the current status of health care from a variety of experts.

Dennis Weissman, President and Publisher of Washington G-2 Reports in Washington, D.C. will present the Keynote address for the Conference. This year's session is entitled *The Medicare Makeover: What It Will Mean for Labs*. Those who have heard Dennis speak in the past know that his presentation will be very dynamic and thought-provoking.

Michael Astion, MD, PhD, Associate Professor at the University of Washington Department of Laboratory Medicine in Seattle, will present two sessions at this year's Conference. The first presentation entitled *Patient Safety and the Clinical Laboratory* will provide an overview of patient safety issues related to clinical laboratory testing and address how any clinical laboratory can perform a quality improvement project to understand when their service problems are most likely to injure patients. His second presentation, entitled *How Physicians Interpret Laboratory Tests*, will review how physicians use predictive value theory to interpret clinical laboratory tests, why very few tests are useful to screen for disease in asymptomatic populations, and review some basic laboratory ordering and interpretation information for five or six common clinical scenarios.

Jeffrey Thompson, MD, MPH, Chief Medical Officer of the Washington State Medical Assistance Administration, will present a session entitled *Medical Necessity: A Misunderstood Concept*. Washington Medicaid is systematically examining processes to better define medical necessity, evidence based medicine practices, and new technology in contracting, and administrative code. This talk will review the rationale, current and proposed WAC changes, and processes to cover/purchase new technology in the future.

Marguerite Busch, Compliance Officer for Pathology Associates Medical Laboratories in Spokane, will present a session entitled *So - How Has HIPAA Impacted YOUR Laboratory? A Frequently Asked Question Presentation Based on Your Input*. The HIPAA Privacy Rules have now been in effect for several months. No matter how well we all prepared to be in compliance with these new rules, most healthcare providers have faced challenges as they implemented new policies and procedures. Questions or concerns about HIPAA implementation were solicited from last year's Conference registrants. These questions will be answered during this session.

continued on page 3

Inside This Issue

- 2,3 Proficiency Testing - Time to Enroll for 2004 Conference, continued
- 4 Waived Testing Helpful Hints/Calendar of Events

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

| | |
|---------------------------|-----------------------|
| Anemia | Lipid Screening |
| ANA | Point-of-Care Testing |
| Bioterrorism Event Mgmt | PSA |
| Bleeding Disorders | Red Cell Transfusion |
| Chlamydia | Renal Disease |
| Diabetes | STD |
| Group A Strep Pharyngitis | Thyroid |
| Hepatitis | Tuberculosis |
| HIV | Urinalysis |
| Intestinal Parasites | Wellness |

Proficiency Testing - Time to Enroll for 2004

by Leonard Kargacin

Proficiency testing (PT), as required under Medical Test Site rule WAC 246-338-050, is a source of external quality control. This practice of testing unknown specimens from an outside source provides an additional means to assure quality laboratory testing results. Although labs perform daily internal quality control with their test systems, external quality control provides important interlaboratory comparisons to determine the accuracy and reliability of your testing procedures.

Between now and December is the time to enroll to be sure you receive PT samples in 2004. A listing of the currently approved PT programs and their phone numbers and website addresses can be found on page 3. Call the programs for a free copy of their 2004 PT brochure or visit their websites. If you are enrolled in PT for 2003, your current PT provider will automatically send you a PT order form and catalog for 2004. Remember, if you do not enroll quickly you will not be guaranteed to receive samples for the first testing event that occurs between January-March 2004 and will receive 0% for non-participation. This is a failure, and may jeopardize your ability to continue testing patient specimens. When finding a PT program to meet your needs:

- Shop around for prices and test groups
- Enroll in more than one company if necessary to cover all tests.

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Website addresses:

DOH home page: <http://www.doh.wa.gov>
LQA home page: <http://www.doh.wa.gov/lqa.htm>
PHL home page: <http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

Information needed to enroll: Complete the 2004 Order Form in the PT brochure with the following information:

- Name (use the NAME **exactly** as it appears on your MTS license)
- Address
- CLIA ID # (our primary means of identifying your laboratory)
- MTS license number (see your MTS license)
- Select the appropriate program for your lab (you may have to enroll in several modules and/or companies to cover all analytes)

NOTE: Be sure to indicate on the enrollment form that copies of your PT results must be sent to the Washington State Department of Health Office of Laboratory Quality Assurance; **this must be done for each analyte!**

Regulated analytes:

- Regulated analytes must be covered by five sample modules shipped three times per year.
- Regulated analytes are listed on the LQA website at www.doh.wa.gov/lqa.htm (Proficiency Testing).
- Don't forget that **non-waived** tests for Influenza A and B, and Direct Strep Antigen must be covered by PT.
- Some manufacturers of waived tests allow laboratories to choose if they want to perform the test as a waived test following the waived test requirements or as a moderate complexity test following these requirements. If the laboratory chooses to perform the test as a moderate complexity test, it **must** participate in a **5-sample PT program three times per year**.

Non-regulated analytes: All non-waived tests other than the regulated analytes must be tested using one or a combination of the following:

- A two-sample PT program from one of the proficiency testing providers
- Blind samples with known values
- Split samples with another lab
- Split samples with another instrument or method
- Correlate patient results with clinical history
- Kodachromes of microscopic tests
- Two analysts perform microscopic test and compare results.

Adding tests during the year:

- Notify our office within 30 days
- Enroll in PT for regulated analytes before you start testing patient samples.

continued on page 3

Proficiency Testing, continued from page 2

Deleting tests during the year:

• Notify our office within 30 days.

Temporarily discontinuing tests during the year:

• Notify our office that the test was temporarily discontinued and the reason why

• Indicate on PT form that test was not performed for this event using the code listed in your PT material

• Notify our office when the test is reinstated.

Test Classification Website: The FDA has a new website available for looking up the complexity classification (waived, moderate, high) of test systems. The website address is: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>

If you have other questions regarding proficiency testing, contact Leonard Kargacin at (206) 361-2804.

Approved Proficiency Testing Providers

| | | |
|----------------------------------|----------------|--|
| Accutest | (800) 665-2575 | www.accutest.org/index.html |
| Amer. Acad. of Family Physicians | (800) 274-7911 | www.aafp.org/pt |
| Amer. Assoc. of Bioanalysts | (800) 234-5315 | www.aab.org |
| American Proficiency Institute | (800) 333-0958 | www.api-pt.com |
| ASIM Medical Lab Evaluation | (800) 338-2746 | www.acponline.org/mle/ |
| California Thoracic Society | (714) 730-1944 | www.thoracic.org/chapters/state/california/ca.html |
| College of American Pathologists | (800) 323-4040 | www.cap.org |
| EXCEL (CAP) | (800) 323-4040 | www.cap.org |
| WSLH | (800) 462-5261 | www.slh.wisc.edu/pt/index.html |

NOTE: The Idaho Bureau of Laboratories proficiency testing program will not be available for 2004. If you are currently using the Idaho PT program, you must find another PT provider for 2004.

Laboratory Conference, continued from page 1

WHO SHOULD ATTEND?

Laboratory Directors
Laboratory / Office Managers
Department Supervisors
Bench Personnel
Billing Personnel
Compliance Officer

The Conference offers something pertinent for everyone whether you work in a physician office laboratory, an independent laboratory, or a small or large hospital.

LOCATION

The Conference this year will be held at the Seattle Marriott Sea-Tac Airport that has easy access from Interstate 5 and the airport. Conference programs and registration information were mailed in mid-September. If you did not receive your Conference Registration Flyer or have questions, contact information is found on page 2. The registration fee will be \$95.00 per person and will include a continental breakfast, breaks and lunch. **MAKE YOUR PLANS TO ATTEND TODAY.**

Waived Testing Helpful Hints

This is a list of the Good Laboratory Practices that have been discussed in the last several issues of Elaborations:

- ✓ Have the correct request and collect a good specimen
- ✓ Label and store the specimen properly
- ✓ Check the expiration date of the test kit
- ✓ Know the package insert
- ✓ Follow the procedure exactly
- ✓ Run controls often
- ✓ Repeat the test if there is a problem
- ✓ Accurately record results
- ✓ Sign and date the results
- ✓ Report the results to the provider

NOTE: Check this spot in future editions of Elaborations for more helpful hints with waived testing.

Calendar of Events

PHL Training Classes:

(<http://www.doh.wa.gov/EHSPHL/PHL/train.htm>)

Urine Sediments

October 10

Shoreline

Shipping & Handling Biohazardous Materials

October 30

Shoreline

Northwest Medical Laboratory Symposium

October 22-25

Olympia

10th Annual Clinical Laboratory Conference

November 10

Seattle

WSSCLS/NWSSAMT Spring Meeting

April 29 - May 1, 2004

Vancouver

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.